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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,445	11/01/2000	Jesus Prieto Valtuena	U013039-2	8974
140	7590	02/25/2004	EXAMINER	
LADAS & PARRY 26 WEST 61ST STREET NEW YORK, NY 10023			SEHARASEYON, JEGATHEESAN	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/674,445	Applicant(s) PRIETO VALTUENA ET AL.	
	Examiner Jegatheesan Seharaseyon	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-22 is/are pending in the application.
- 4a) Of the above claim(s) 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-14 and 16-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to the amendment and remarks filed on 10/24/03. Claims 23-28 have been cancelled. Thus, claims 11-22 are pending.
2. Applicants correction of the specification is acknowledged.
3. It is noted that the Applicant has provided corrected drawings in response to the previous Office Action.
4. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Objections

5. Claim 15 is objected to because of the following informalities: Applicant amended the claim to change the scope of the claims to include gene therapy, which not present in the original claims. Thus, claim 15 will not be examined further.

Claim Rejections - 35 USC § 112, withdrawn.

6. Rejection of claims 11, 16, 21, 22 and 23 as vague and indefinite under 35 USC § 112 2nd paragraph is withdrawn in view of Applicant's arguments and amendment filed on 10/24/03.

Claim Rejections - 35 USC § 112 1st paragraph, withdrawn

7. Claims 11, 16, 21, 22 and 23 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is withdrawn in view of Applicant's arguments and amendment filed on 10/24/03.

Claim Rejections - 35 USC § 102, withdrawn

8. Rejection of claims 11-14, 21 and 23-27 under 35 U.S.C. 102 (b) as being anticipated by Foster et al. (1996) is withdrawn because of Applicants persuasive arguments and the amendment to claim 11.

9. The rejection of claims 11-14, 21 and 23-27 under 35 U.S. C. 102(e) as being anticipated by Foster et al. (U. S. Patent no. 6, 007, 805) is withdrawn because Applicant has amended claim 11.

Claim Rejections - 35 USC § 103, withdrawn

10. The rejection of claims 16-19 under 35 U.S.C. 103 (a) as being unpatentable over Foster (1996) or Foster et al. (U. S. Patent No. 6,007,805) in view of Wallner et al. (U.S. Patent No. 5, 914, 111) is withdrawn in light of the persuasive arguments presented with reference to Foster et al. (1996).

11. The rejection of claim 20 under 35 U.S.C. 103 (a) as being unpatentable over Foster (1996) or Foster et al. (U. S. Patent No. 6,007,805) in view of Wallner et al. (U.S. Patent No. 5, 914, 111) and further in view of Salmanian et al. (1996) is also withdrawn in light of the persuasive arguments presented with reference to Foster et al. (1996).

12. New grounds of rejection.

Claim Rejections - 35 USC § 103

13. Claims 11-14 and 16-22 and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foster et al. (U.S. Patent No: 6,007,805) in view of Albrecht (6, 172,046).

The instant invention is directed to treating a patient having liver disease of viral origin with IFN α -5.

Foster et al. (U. S. Patent No. 6,007,805) teaches the use of IFN α subtype in the preparation of a medicament (pharmaceutical formulation) for preventing or treating viral infections of a particular organ or cell type (column 2, lines 56-60). It also teaches that the particular IFN α subtype to be used in clinical practice will depend on the cell type that is infected (column 2, lines 5-7). It teaches that IFN α -5 has very potent antiviral activity in liver cells. It also demonstrates the relative ED50 for various interferon subtypes including IFN α -5 in three different cell lines (Fig 1A-1C). However, it does not teach specific virus such as HCV causing diseases related to the liver or recite the diseases. It also does not teach the use of IFN α in patients having chronic hepatitis C infection. Albrecht teaches that chronic infection with hepatitis C virus can cause hepatitis C eventually resulting in cirrhosis of the liver, decompensated liver disease and/or hepatocellular carcinoma (column, 1 lines 6-12). The reference also teaches the use IFN α in patients having chronic hepatitis C infection to radicate HCV (column 1, lines 50-53).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time invention was made to treat patients with chronic hepatitis C infection related liver diseases caused by hepatitis C virus by using IFN α -5 protein disclosed in Foster et al. because Albrecht provide the motivation to treat patients with chronic HCV infection with IFN α proteins and the potent antiviral effect of IFN α -5 in liver cells disclosed by Foster et al., with a reasonable expectation of success. Therefore, the

claims are obvious over Foster et al. (U.S. Patent No: 6,007,805) in view of Albrecht (6,172,046) and Wallner et al. (U.S. Patent No: 5,914,111).

It is noted that claims 17-20 are directed to a product by process method. Thus, the recombinant methods used to produce IFN α -5 protein do not have a patentable weight. In addition, it is the position of the Office that, absent evidence to the contrary, the IFN α -5 protein produced by any of the claimed method will be identical to the protein described by Foster et al.

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. Wallner et al. (U.S. Patent No: 5,914,111). Wallner et al. have demonstrated the recombinant expression LFA-3. It is noted at the time the invention was made cloning of genes into vectors for the expression in prokaryotic as well as eukaryotic host cells was routine in the art for the purpose of producing recombinant proteins.

2. Salmanian et al. (1996). Salmanian et al. discloses the expression of human epidermal growth factor protein in eukaryotic host *Solanum tuberosum* by recombinant methods (see abstract).

15. No claims are allowable.

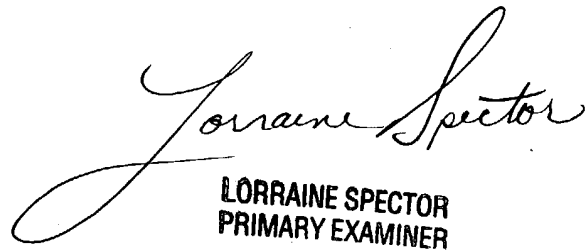
Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS


**LORRAINE SPECTOR
PRIMARY EXAMINER**